American Bakers Association
Serving the Baking Industry Since 1897

June 6, 2005

Ms. Cynthia Oshita
Office of Environmental Health Hazard Assessment
P.O. Box 4010
Sacramento, CA 95812-4010

Re: Proposed Rulemaking to Establish a Limited Exemption From the Warning Requirements of the Safe Drinking Water and Toxic Enforcement Act of 1986 for Exposures to Listed Chemicals that Form in Food as a Result of Naturally Occurring Constituents in the Food Being Cooked or Heat Processed

Dear Ms. Oshita:

These comments are submitted on behalf of the American Bakers Association ("ABA") regarding the proposal by the Office of Environmental Health Hazard Assessment ("OEHHA") to establish by regulation a limited exemption from the warning requirements of the Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65" or the "Act") for exposures to listed chemicals that form in food as a result of naturally occurring constituents in the food being cooked or heat processed (a "cooking exemption"). ABA is the national trade association representing the wholesale baking industry. Our membership consists of bakers and bakery suppliers who together are responsible for the manufacture of approximately 80 percent of the baked goods sold in the United States. ABA has a substantial interest in this proposed rulemaking because it would affect potential warning requirements regarding acrylamide for nearly all baked goods.

ABA strongly supports a cooking exemption from the Proposition 65 warning requirements. A food that would not be subject to Proposition 65 in its raw form should not be regulated under the Act solely because it is cooked or heated. Such traditional methods of food preparation have been occurring since the discovery of fire, and people have safely consumed cooked and heated foods for thousands of years. A cooking exemption would be consistent with the purposes of Proposition 65, national dietary guidance, and science-based public health considerations.

While ABA recognizes that the proposed cooking exemption would relate to more than just acrylamide, ABA's comments are focused on this substance because it is the listed chemical that has been detected in baked goods. ABA is part of a coalition of the major food associations and supports the comments submitted by that coalition and other members. ABA's individual comments touch upon the general issues implicated by the proposed rulemaking but are focused primarily upon the issues relating to a cooking exemption as applied to baked goods.

A Cooking Exemption Would Further the Purposes of Proposition 65

Chemicals formed from natural constituents in foods through cooking and heating plainly were not intended to fall within the ambit of Proposition 65. The focus of that proposition was upon chemicals "put out into the environment." See Ballot Pamphlet, Argument in Favor of Proposition 65, as presented to the voters, Nov. 4, 1986. It is inconceivable that the drafters of the proposition and the citizens who voted for it intended the Act to impose warning requirements regarding constituents formed even in their own homes through the everyday act of cooking or preparing food. Traditional food preparation methods of cooking and heating do not result in an "exposure" within the meaning of section 25249.6 of the Act, which provides that "[n]o person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual." (Emphasis added.) Those who cook food do not intentionally expose others to chemicals; they merely intend to provide them with food in palatable form. For example, bakers do not intentionally expose consumers to acrylamide; bread and other baked goods simply cannot be cooked without this result.

Not only is there no benefit under Proposition 65 to warnings about chemicals formed during cooking, but also the requirement of such warnings would undermine the legitimate public health and safety goals of the Act by overwarning in a manner that inures the public to meaningful warnings, misleading consumers as to the nature of the risk, fostering unjustifiable inconsistency in implementation, and siphoning State and industry resources away from chemicals of legitimate concern.

Given the enormous range of foods in which acrylamide has been detected –including in coffee, potato chips, bread, olives, and prune juice – warnings would need to appear on a substantial proportion of foods consumers are accustomed to purchasing. Such an abundance of warnings would diminish the overall significance of Proposition 65 warnings, particularly when consumers will feel compelled to ignore the warnings and go ahead and purchase such staple goods as bread and cereal. Moreover, as OEHHA's predecessor agency, the California Health and Welfare Agency ("HEW"), recognized when establishing an exemption for chemicals "naturally occurring" in food, "[o]ne of the purposes of the Act is to inform the consumer about the presence of toxic chemicals and to facilitate the ability of the consumer to choose among exposures. Food is a basic daily necessity of life on a par with the water that we drink and the air that we breathe." Final Statement of Reasons, Title 22, Cal. Code of Regs. Section 12501 at 4-5. HEW acknowledged that "warnings for naturally occurring chemicals in food would not significantly enlighten the consumer about his or her options." *Id.* at 5. The same logic holds true for warnings on the extensive breadth of foods containing acrylamide; that is, warnings would not significantly inform consumers about their options because they would be so abundant that consumers could not choose among exposures without compromising the nutritional quality of their diets.

Warnings on foods in which chemicals are formed through cooking from natural constituents could also mislead consumers into thinking that such chemicals are only a hazard in store-bought food. In fact, with respect to acrylamide, the federal Food and Drug Administration has expressed concern that consumer exposure may be greatest through home cooking. See Letter from Deputy Commissioner Lester M. Crawford to Joan E. Denton, Director, OEHHA, July 14, 2003, at 2 ("Crawford Letter"). At a minimum, consumers scared by warnings into substituting home baked goods for purchased varieties would be exposed to the same level of acrylamide, and therefore the warning would fail to accomplish any reduction in exposure.

Requiring warnings for chemicals formed through cooking would also create confusion as a result of inconsistency with other established provisions implementing Proposition 65, namely, the "naturally occurring" exemption at Section 12501. There is no meaningful toxicological, health, or policy difference between exposure to chemicals produced by cooking and exposures to chemicals that otherwise occur naturally in foods, and therefore no justification for a regulatory scheme that would treat such exposures differently. There is no more "human activity" involved in cooking food than there is in growing food. Obviously, it takes human activity to plant, cultivate, harvest, and process food. To say that cooking alters the "natural" state of food but these latter activities do not is to ignore the plain facts of food production and preparation. Many food products, indeed, are either inedible or nonexistent without food processing. Raw meat is clearly inedible. Bread does not exist without processing. Cooked meat and bread, however, are still entirely natural products. For purposes of logical consistency, "naturally occurring" chemicals and those formed through cooking from natural constituents in foods should be equally exempt from the warning requirements of Proposition 65.

Finally, it must be recognized that Section 12703(b)(1), which provides for the availability of an alternative risk level when supported by sound considerations of public health, such as "where chemicals in food are produced by cooking necessary to render the food palatable or to avoid microbiological contamination," does not provide a viable mechanism for addressing all possible listed chemicals that may be discovered in foods at varying levels. It is far preferable to exclude chemicals formed during cooking from natural constituents in foods from Proposition 65 completely, rather than retain them within the scope of the Act and require the establishment of no significant risk levels ("NSRLs") and alternative risk levels for each constituent. To take the latter approach, it will be necessary to engage in substantial rulemaking to establish specific risk levels for each and every chemical produced in the course of processing each and every food consumed in the State of California. This effort raises extraordinarily complex issues that will require a major expenditure of State and industry resources. Indeed, the regulatory history to date reflects the difficulty in establishing an accurate and reliable NSRL for acrylamide, as indicated by the recent proposal to change the NSRL from 0.2 μg/day to 1.0 μg/day and establish an alternative risk level for acrylamide in breads and cereals. Moreover, despite active efforts across the globe to determine whether and at what level acrylamide exposures through food may cause harm, the matter remains unsettled. Even if a valid alternative risk level could be established for acrylamide, it would not likely be employed as a practical matter, given the

documented variability in acrylamide levels even among production lots of the same food products. See FDA/CFSAN - Acrylamide Questions and Answers, No.8, available at http://www.cfsan.fda.gov/~dms/ acryfaq.html ("FDA Q&A"). Food processors would be inclined to err on the side of warning if they could not assure that every batch of product would fall under the alternative risk level, thus leading to unnecessary warnings on food products that posed no actual risk.

For the foregoing reasons, including chemicals formed during cooking within the purview of Proposition 65 in no way furthers the purposes of that Act, but instead hinders its public health and safety function in a number of respects.

A Cooking Exemption Would Further Compliance with National Dietary Guidance and Other Science-Based Public Health Considerations

The Dietary Guidelines for Americans 2005, issued jointly by the U.S. Department of Health and Human Services ("HHS") and U.S. Department of Agriculture ("USDA"), and ensuing revised USDA Food Guide Pyramid continue to emphasize the importance of grain-based food products as a foundation of a healthy diet. In particular, the Guidelines encourage increased consumption of whole grain products for their fiber content, but also recognize the importance of enriched grain products in helping consumers achieve adequate nutrient intake, including folic acid for women of childbearing age to reduce the risk of neural tube defects.

In the absence of a cooking exemption, a Proposition 65 warning would be required on the substantial majority of grain-based foods encouraged by national dietary guidance. While boiled grain foods in which acrylamide is not formed, such as rice or corn, could comprise some of the grain products in the diet, consumers are unlikely to consume the recommended six to eleven servings of grain products from these categories alone. Rather, Americans seeking to meet dietary recommendations will aim to get their grain servings from staples such as bread and cereal. Most of these foods cannot be cooked through methods other than high heat baking or frying, although palatability concerns inherently impose limits upon excessive browning that may increase acrylamide formation.

The appearance of an acrylamide warning on virtually all of these staple grain-based foods could deter consumers from eating such foods, to their nutritional detriment. To avoid this result, FDA communications regarding acrylamide have repeatedly emphasized that, given the little that is known about this chemical in food, consumers should "eat a balanced diet, choosing a variety of foods that are low in trans fat and saturated fat, and rich in high-fiber grains, fruits, and vegetables." FDA Q&A, No. 11. Indeed, OEHHA's proposed warning language for acrylamide would include this FDA recommendation. The juxtaposition of this dietary guidance with the acrylamide cancer warning would undoubtedly lead to widespread consumer confusion

arising from apparently conflicting messages about the healthfulness of a food subject to the warning.

Notably, a well-established benefit of consuming fiber-rich grain products is the reduction in cancer risk. Indeed, FDA promulgated a health claim for fiber-containing grain products, fruits and vegetables and reduced risk of cancer based upon significant scientific agreement supporting the diet/disease relationship. 21 C.F.R. § 101.76. Without a cooking exemption, however, a bread product eligible to bear this health claim would also be required to bear a warning that the product contains acrylamide which may increase the risk of cancer. This illogical result seems even more egregious when one considers that the health claim is based upon extensive scientific evidence proving the health benefit, whereas studies to date have not shown an increased cancer risk with acrylamide exposure. See FDA Action Plan for Acrylamide in Food, March 2004, at 2, available at http://www.cfsan.fda.gov/~dms/acrypla3.html ("FDA Action Plan").

Ample scientific evidence also demonstrates the benefits of cooking food to destroy harmful pathogens. In response to a Proposition 65 warning linking cooking to the formation of a cancer-causing substance, however, businesses and consumers may undercook foods in an attempt to reduce that chemical in the food, and may inadvertently increase the risk of microbiological contamination. Again, in such a circumstance, the scientifically unsubstantiated "risk" of acrylamide would be given greater weight, by the warning language, than the threat that has been well-established.

A cooking exemption would further public health and safety priorities, and in turn the purposes of Proposition 65, by removing barriers to compliance with national dietary guidelines and safe cooking and handling practices. The exemption is particularly justified in light of the inadequate scientific evidence at this time regarding the risk of chemicals formed in cooking, as compared to the well-supported relationships between diet and health and established food safety practices.

A Cooking Exemption Must Be Drafted in Language that is Clear and Meaningful to Businesses and Consumers

In order to provide clear and unambiguous guidance, to both businesses and consumers, as to what constitutes an "exposure" within the meaning of Proposition 65, any cooking exemption must be concrete and meaningful. The proposed language allowing the cooking exemption only where "the concentration of the chemical in question has been reduced to the lowest level currently feasible using good cooking and manufacturing processes" is meaningless in light of what is currently known about the formation of acrylamide and potential mechanisms to reduce its concentration in cooked foods.

At present there is simply no known means to safely reduce the level of acrylamide in foods generally. FDA noted in its Action Plan that "at this time, not enough is known about acrylamide formation to identify safe, effective, and practical modifications to food processing techniques that will clearly prevent or reduce formation." Action Plan at 2. Dr. Crawford

emphasized in his letter to Dr. Denton that "[m]ore information is needed on the risks to humans from acrylamide in foods and on whether and how acrylamide levels in food can be safely reduced." Crawford Letter at 1. Without any known methods of reducing the level of acrylamide in food, the proviso mandating reduction to the lowest level feasible essentially wipes out the cooking exemption because food processors will be unable to comply with the conditions for exemption.

Significantly, food authorities have warned that potential methods for reducing acrylamide formation in foods could lead to unanticipated harmful consequences, and will require adequate study before implementation. In the recent Summary and Conclusions of the Sixty-Fourth Meeting of the Joint FAO/WHO Expert Committee on Food Additives ("JECFA"), February 2005, the Committee discussed a number of possible options to mitigate acrylamide formation but stated that the "feasibility of adapting these methods to large-scale food processing has not been completely studied in most cases. Furthermore, any major changes would need to be checked for consumer acceptability, nutritional quality, and the possible increased formation of other undesirable substances." JECFA/64/SC at 13. FDA similarly cautioned that "any warning label requirements imposed under Proposition 65 might encourage manufacturers to take premature steps to remove acrylamide from food by introducing additives or changing cooking processes. Such steps could have unforeseen adverse consequences on public health if the consequences . . . are not scientifically and thoughtfully considered." Crawford Letter at 2-3. Given the concerns expressed by these authorities, the regulatory language for a cooking exemption should not mandate attempts to reduce formation of a chemical in food, where no methods for doing so have been established as safe and effective. Without such methods, the proposed regulatory language is not only meaningless but also potentially harmful to the public because it provides detrimental incentives to food processors to try methods of chemical reduction that may result in more harm than good.

ABA's principal concern remains the best interests of consumers and assuring the provision of safe, wholesome, and nutritious baked goods. For this reason, ABA supports meaningful rulemaking that would establish an exemption from Proposition 65 for chemicals formed through cooking from natural constituents in foods. ABA appreciates the opportunity to comment on this issue of substantial importance to the baking industry.

Respectfully submitted,

Lee Sanders
Vice President
Regulatory & Technical Services

Paul C. Abenante
President & CEO

cc: Dr. Joan Denton